CorMedix Inc.
Form 10-Q
May 10, 2016

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

ý QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2016

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number 001-34673

CORMEDIX INC.
(Exact Name of Registrant as Specified in Its Charter)

| Delaware | 20-5894890 |
|---|---|
| (State or Other Jurisdiction of Incorporation or Organization) | (I.R.S. Employer Identification No.) |
| 1430 US Highway 206, Suite 200, Bedminster, NJ | 07921 |
| (Address of Principal Executive Offices) | (Zip Code) |

(908) 517-9500
(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ý No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ý No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer,

or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

| | |
|---|---|
| Large accelerated filer ¨ | Accelerated filer ý |
| Non-accelerated filer ¨ (Do not check if a smaller reporting company) | Smaller reporting company ¨ |

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No ý

The number of shares outstanding of the issuer's common stock, as of May 6, 2016 was 36,218,323.

CORMEDIX INC. AND SUBSIDIARY

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PART I

FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements.

CORMEDIX INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

| | March 31, 2016 | December 31, 2015 |
|---|---|---|
| ASSETS | | |
| Current assets | | |
| Cash and cash equivalents | $13,184,776 | $11,817,418 |
| Restricted cash | 171,553 | 171,553 |
| Short-term investments | 17,043,990 | 23,568,386 |
| Trade receivables | 344,727 | 315,771 |
| Inventories, net | 333,873 | 376,569 |
| Prepaid research and development expenses | 2,171,689 | 430,162 |
| Other prepaid expenses and current assets | 319,198 | 379,004 |
| Total current assets | 33,569,806 | 37,058,863 |
| Property and equipment, net | 34,777 | 37,866 |
| Security deposit | 5,000 | 5,000 |
| TOTAL ASSETS | $33,609,583 | $37,101,729 |
| | | |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities | | |
| Accounts payable | $1,581,417 | $1,709,397 |
| Accrued expenses | 1,346,925 | 1,221,557 |
| Deferred revenue | 135,407 | 130,409 |
| Total current liabilities | 3,063,749 | 3,061,363 |
| Deferred revenue, long-term | 26,622 | 28,878 |
| TOTAL LIABILITIES | 3,090,371 | 3,090,241 |
| | | |
| COMMITMENTS AND CONTINGENCIES | | |
| | | |
| STOCKHOLDERS' EQUITY | | |
| Preferred stock - $0.001 par value: 2,000,000 shares authorized; 450,085 shares issued and outstanding at March 31, 2016 and December 31, 2015 (see Note 3) | 450 | 450 |
| Common stock - $0.001 par value: 80,000,000 shares authorized; 36,138,323, and 35,963,348 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively | 36,139 | 35,964 |
| Accumulated other comprehensive income | 92,982 | 62,130 |
| Additional paid-in capital | 129,012,409 | 128,304,539 |
| Accumulated deficit | (98,622,768 ) | (94,391,595 ) |
| TOTAL STOCKHOLDERS' EQUITY | 30,519,212 | 34,011,488 |
| TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY | $33,609,583 | $37,101,729 |

See Notes to Unaudited Condensed Consolidated Financial Statements.

CORMEDIX INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
AND COMPREHENSIVE LOSS

(Unaudited)

| | Three Month Periods Ended March 31, | |
|---|---|---|
| | 2016 | 2015 |
| Revenue | | |
| Net sales | $41,427 | $31,264 |
| Cost of sales | (50,229) | (17,319) |
| Gross profit (loss) | (8,802) | 13,945 |
| Operating Expenses | | |
| Research and development | (2,089,592) | (1,234,515) |
| Selling, general and administrative | (2,162,936) | (2,693,102) |
| Total operating expenses | (4,252,528) | (3,927,617) |
| Loss From Operations | (4,261,330) | (3,913,672) |
| Other Income (Expense) | | |
| Interest income | 31,636 | 543 |
| Foreign exchange transaction loss | (487) | (429) |
| Value of warrants issued in connection with backstop financing | - | (1,583,252) |
| Interest expense | (992) | (859) |
| Total income (expense) | 30,157 | (1,583,997) |
| Net Loss | (4,231,173) | (5,497,669) |
| Other Comprehensive Income | | |
| Unrealized gain from investment | (793) | - |
| Foreign currency translation gain | 31,645 | 2,810 |
| Total comprehensive income | 30,852 | 2,810 |
| Comprehensive Loss | $(4,200,321) | $(5,494,859) |
| Net Loss | $(4,231,173) | $(5,497,669) |
| Dividends, including deemed dividends | - | (33,121) |
| Net Loss Attributable To Common Shareholders | $(4,231,173) | $(5,530,790) |
| Net Loss Per Common Share – Basic and Diluted | $(0.12) | $(0.23) |
| Weighted Average Common Shares Outstanding – Basic and Diluted | 36,012,756 | 23,921,605 |

See Notes to Unaudited Condensed Consolidated Financial Statements.

CORMEDIX INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY
(Unaudited)

| | Common Stock | | Non-Voting Preferred Stock – Series C-2, Series C-3, Series D and Series E | | Accumulated Other Comprehen-sive Income | Additional Paid-in Capital | Accumulated Deficit | Total Stockholders' Equity |
|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | | | | |
| Balance at January 1, 2016 | 35,963,348 | $ 35,964 | 450,085 | $ 450 | $ 62,130 | $ 128,304,539 | $ (94,391,595) | $ 34,011,488 |
| Stock issued in connection with sale of common stock | 74,975 | 75 | | | | 149,201 | | 149,276 |
| Stock issued in connection with stock options exercised | 100,000 | 100 | | | | 116,600 | | 116,700 |
| Stock-based compensation | | | | | | 442,069 | | 442,069 |
| Other comprehensive income | | | | | 30,852 | | | 30,852 |
| Net loss | | | | | | | (4,231,173 ) | (4,231,173 ) |
| Balance at March 31, 2016 | 36,138,323 | $ 36,139 | 450,085 | $ 450 | $ 92,982 | $ 129,012,409 | $ (98,622,768) | $ 30,519,212 |

See Notes to Unaudited Condensed Consolidated Financial Statements.

CORMEDIX INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

| | Three Month Periods Ended March 31, | |
|---|---|---|
| | 2016 | 2015 |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Net loss | $(4,231,173) | $(5,497,669) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Stock-based compensation | 442,069 | 1,026,924 |
| Value of warrants issued in connection with backstop financing | - | 1,583,252 |
| Loss on foreign currency transactions | - | 429 |
| Inventory reserve | 22,428 | - |
| Depreciation | 4,072 | 3,158 |
| Changes in operating assets and liabilities: | | |
| Restricted cash | - | (131,994) |
| Trade receivables | (15,498) | 2,304 |
| Inventory | 20,268 | 1,624 |
| Prepaid expenses and other current assets | (1,679,728) | (76,146) |
| Accounts payable | (130,207) | 546,379 |
| Accrued expenses | 119,437 | 197,150 |
| Deferred revenue | (2,256) | (3,708) |
| Net cash used in operating activities | (5,450,588) | (2,348,297) |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Sale of short-term investments | 6,547,842 | - |
| Purchase of equipment | - | (12,944) |
| Net cash provided by (used in) investing activities | 6,547,842 | (12,944) |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Proceeds from sale of common stock from at-the-market program | 149,276 | - |
| Proceeds from exercise of warrants | - | 6,702,168 |
| Proceeds from exercise of stock options | 116,700 | 125,500 |
| Net cash provided by financing activities | 265,976 | 6,827,668 |
| Foreign exchange effect on cash | 4,128 | (6,639) |
| NET INCREASE IN CASH | 1,367,358 | 4,459,788 |
| CASH – BEGINNING OF PERIOD | 11,817,418 | 4,339,540 |
| CASH – END OF PERIOD | $13,184,776 | $8,799,328 |
| Cash paid for interest | $992 | $859 |
| Supplemental Disclosure of Non-Cash Financing Activities: | | |
| Conversion of preferred stock to common stock | $- | $500 |
| Unrealized loss from investments | $(793) | $- |
| Conversion of wages and fees to common stock | $- | $18,750 |
| Dividend, including beneficial conversion feature | $- | $33,121 |

See Notes to Unaudited Condensed Consolidated Financial Statements.

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CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 1 — Organization, Business and Basis of Presentation:

Organization and Business

CorMedix Inc. ("CorMedix" or the "Company"), a commercial pharmaceutical and medical device company, was incorporated in the State of Delaware on July 28, 2006. The Company in-licenses, develops and commercializes prophylactic and therapeutic products for the prevention and treatment of infectious diseases and inflammatory diseases. In 2013, the Company formed a wholly-owned subsidiary, CorMedix Europe GmbH.

The Company's primary activities since incorporation have been acquiring licenses for its pharmaceutical product candidates, performing business and financial planning, performing research and development, seeking regulatory approval for its products and conducting initial commercialization activities for its product Neutrolin® in certain markets. The Company has in-licensed the worldwide rights to develop and commercialize its product candidate, CRMD003 (Neutrolin®).

The Company launched its Phase 3 clinical trial in hemodialysis catheters in the United States ("U.S.") in December 2015. The clinical trial named Catheter Lock Solution Investigational Trial, or LOCK-IT-100 is a prospective, multicenter, randomized, double-blind, placebo-controlled, active control trial which aims to demonstrate the efficacy and safety of Neutrolin in preventing catheter-related bloodstream infections, or CRBSI, in subjects receiving hemodialysis therapy as treatment for end stage renal disease. The primary endpoint for the trial is freedom from CRBSI. The trial will evaluate whether Neutrolin is superior to the active control heparin by documenting the incidence of CRBSI and the time until the occurrence of CRBSI. Key secondary endpoints are catheter patency which is defined as required use of tissue plasminogen activating factor (tPA) or removal of catheter due to dysfunction and catheter removal for any reason. An exploratory endpoint of biofilm analysis will be evaluated in the first 200 catheters removed. The Company also plans to conduct a Phase 3 clinical trial in oncology/total parenteral nutrition that is estimated to start in the first quarter of 2017.

The Company received CE Mark approval for Neutrolin in 2013 and began the commercial launch of Neutrolin in Germany for the prevention of catheter-related bloodstream infections and maintenance of catheter patency in hemodialysis patients using a tunneled, cuffed central venous catheter for vascular access. To date, Neutrolin is registered and may be sold in Austria, Germany, Italy, Malta, Saudi Arabia, Bahrain, Qatar, Kuwait, United Arab Emirates and The Netherlands for such treatment.

In September 2014, the TUV-SUD and The Medicines Evaluation Board of the Netherlands granted a label expansion for Neutrolin for expanded indications for the European Union ("EU"). In December 2014, the Company received approval from the Hessian District President in Germany to expand the label to include use in oncology patients receiving chemotherapy, IV hydration and IV medications via central venous catheters. The expansion also adds patients receiving medication and IV fluids via central venous catheters in intensive or critical care units (cardiac care unit, surgical care unit, neonatal critical care unit, and urgent care centers). An indication for use in total parenteral, or IV, nutrition was also approved.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial information

and with the instructions for Form 10-Q and Article 10 of Regulation S-X. Accordingly, the unaudited condensed consolidated financial statements do not include all information and footnotes required by GAAP for complete annual financial statements. In the opinion of management, the accompanying unaudited condensed consolidated financial statements reflect all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation of such interim results. Interim operating results are not necessarily indicative of results that may be expected for the full year ending December 31, 2016 or for any subsequent period. These unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto of the Company which are included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on March 15, 2016. The accompanying condensed balance sheet as of December 31, 2015 has been derived from the audited financial statements included in such Form 10-K.

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 2 — Summary of Significant Accounting Policies:

Liquidity, Risks and Uncertainties

The Company's operations are subject to a number of factors that can affect its operating results and financial condition. Such factors include, but are not limited to: the results of clinical testing and trial activities of the Company's product candidates; the ability to obtain regulatory approval to market the Company's products; competition from products manufactured and sold or being developed by other companies; the price of, and demand for, Company products; the Company's ability to negotiate favorable licensing or other manufacturing and marketing agreements for its products; and the Company's ability to raise capital to support its operations.

To date, the Company's commercial operations have not generated enough revenues to make the Company profitable. As of March 31, 2016, the Company had an accumulated deficit of $98.6 million, and incurred losses from operations of $4.3 million for the quarter then ended. Based on the current development plans for Neutrolin in both the U.S. and foreign markets (including the ongoing hemodialysis Phase 3 clinical trial in the U.S.) and our other operating requirements, management believes that the existing cash at March 31, 2016 will be sufficient to fund operations for at least the next twelve months following the balance sheet date. The Company will need additional funding thereafter to complete the hemodialysis clinical trial in the U.S. which commenced in December 2015. The Company also plans to initiate an oncology/total parenteral nutrition trial in the U.S. in the first quarter of 2017 and will need to raise additional funds to commence and complete this trial. If the Company is unable to raise additional funds when needed, they will not be able to complete the ongoing hemodialysis Phase 3 clinical trial or the planned Phase 3 oncology/total parenteral nutrition clinical trial.

The Company's continued operations will depend on its ability to raise additional capital through various potential sources, such as equity and/or debt financings, strategic relationships, or out-licensing of its products, until it achieves profitability, if ever. However, the Company can provide no assurances that such financing or strategic relationships will be available on acceptable terms, or at all. Without this funding, the Company could be required to delay, scale back or eliminate some or all of its research and development programs which would likely have a material adverse effect on the Company's business.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Basis of Consolidation

The condensed consolidated financial statements include the accounts of the Company and CorMedix Europe GmbH, a wholly owned subsidiary. All significant intercompany accounts and transactions have been eliminated in consolidation.

Cash and Cash Equivalents

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents. The Company maintains its cash and cash equivalents in bank deposits and other interest bearing accounts, the balances of which exceed federally insured limits.

Short-Term Investments

The Company determines the appropriate classification of marketable securities at the time of purchase and reevaluates such designation as of each balance sheet date. Investments in marketable debt and equity securities classified as available-for-sale are reported at fair value. Fair values of the Company's investments are determined using quoted market prices in active markets for identical assets or liabilities or quoted prices for similar assets or liabilities or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Changes in fair value that are considered temporary are reported net of tax in other comprehensive income (loss). Realized gains and losses, amortization of premiums and discounts and interest and dividends earned are included in income (expense) on the condensed consolidated statements of operations and comprehensive income (loss). The cost of investments for purposes of computing realized and unrealized gains and losses is based on the specific identification method. For declines in the fair value of equity securities that are considered other-than-temporary, impairment losses are charged to other (income) expense, net. The Company considers available evidence in evaluating potential impairments of its investments, including the duration and extent to which fair value is less than cost. There were no deemed permanent impairments at March 31, 2016.

The Company's marketable securities are highly liquid and consist of U.S. government agency securities, high-grade corporate obligations and commercial paper with original maturities of more than 90 days. As of March 31, 2016, all of the Company's investments had contractual maturities which were less than one year. The following table summarizes the amortized cost, unrealized gains and losses and the fair value at March 31, 2016 and December 31, 2015 of the Company's financial assets that are measured on a recurring basis:

| March 31, 2016: | Amortized Cost | Gross Unrealized Losses | Gross Unrealized Gains | Fair Value |
|---|---|---|---|---|
| Money Market Funds included in Cash Equivalents | $3,047,206 | $- | $- | $3,047,206 |
| U.S. Government Agency Securities | 2,014,153 | (53) | - | 2,014,100 |
| Corporate Securities | 13,035,370 | (2,215) | 1,475 | 13,034,630 |
| Commercial Paper | 1,995,260 | - | - | 1,995,260 |
| Subtotal | 17,044,783 | (2,268) | 1,475 | 17,043,990 |
| Total March 31, 2016 | $20,091,989 | $(2,268) | $1,475 | $20,091,196 |
| December 31, 2015: | | | | |
| Money Market Funds included in Cash Equivalents | $3,353,067 | $- | $- | $3,353,067 |

| | | | | |
|---|---|---|---|---|
| U.S. Government Agency Securities | 6,531,914 | (3,014) | - | 6,528,900 |
| Corporate Securities | 15,065,595 | (21,637) | 412 | 15,044,370 |
| Commercial Paper | 1,995,116 | - | - | 1,995,116 |
| Subtotal | 23,592,625 | (24,651) | 412 | 23,568,386 |
| Total December 31, 2015 | $26,945,692 | $(24,651) | $412 | $26,921,453 |

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Fair Value Measurements

The Company's financial instruments recorded in the consolidated balance sheets include cash and cash equivalents, accounts receivable, investment securities, accounts payable and accrued expenses. The carrying value of certain financial instruments, primarily cash and cash equivalents, accounts receivable, accounts payable, and accrued expenses approximate their estimated fair values based upon the short-term nature of their maturity dates.

The Company categorizes its financial instruments into a three-level fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The fair value hierarchy gives the highest priority to quoted prices in active markets for identical assets (Level 1) and the lowest priority to unobservable inputs (Level 3). If the inputs used to measure fair value fall within different levels of the hierarchy, the category level is based on the lowest priority level input that is significant to the fair value measurement of the instrument. Financial assets recorded at fair value on the Company's condensed consolidated balance sheets are categorized as follows:

- Level 1 inputs—Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.

- Level 2 inputs— Significant other observable inputs (e.g., quoted prices for similar items in active markets, quoted prices for identical or similar items in markets that are not active, inputs other than quoted prices that are observable such as interest rate and yield curves, and market-corroborated inputs).

- Level 3 inputs—Unobservable inputs for the asset or liability, which are supported by little or no market activity and are valued based on management's estimates of assumptions that market participants would use in pricing the asset or liability.

The following table provides the carrying value and fair value of the Company's financial assets measured at fair value on a recurring basis as of March 31, 2016 and December 31, 2015:

| March 31, 2016: | Carrying Value | Level 1 | Level 2 | Level 3 |
|---|---|---|---|---|
| Money Market Funds | $3,047,206 | $3,047,206 | $- | $- |
| US Government Agency Securities | 2,014,100 | - | 2,014,100 | - |
| Corporate Securities | 13,034,630 | - | 13,034,630 | - |
| Commercial Paper | 1,995,260 | - | 1,995,260 | - |
| Subtotal | 17,043,990 | - | 17,043,990 | - |
| Total March 31, 2016 | $20,091,196 | $3,047,206 | $17,043,990 | $- |
| December 31, 2015: | | | | |
| Money Market Funds | $3,353,067 | $3,353,067 | $- | $- |
| US Government Agency Securities | 6,528,900 | - | 6,528,900 | - |
| Corporate Securities | 15,044,370 | - | 15,044,370 | - |
| Commercial Paper | 1,995,116 | - | 1,995,116 | - |
| Subtotal | 23,568,386 | - | 23,568,386 | - |
| Total December 31, 2015 | $26,921,453 | $3,353,067 | $23,568,386 | $- |

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CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Foreign Currency Translation and Transactions

The condensed consolidated financial statements are presented in U.S. Dollars ("USD"), the reporting currency of the Company. For the financial statements of the Company's foreign subsidiary, whose functional currency is the EURO, foreign currency asset and liability amounts, are translated into USD at end-of-period exchange rates. Foreign currency income and expenses are translated at average exchange rates in effect during the period in which the income and expenses were recognized. Translation gains and losses are included in other comprehensive loss.

The Company has intercompany loans between the parent company based in New Jersey and its German subsidiary. The intercompany loans outstanding are not expected to be repaid in the foreseeable future and unrealized foreign exchange movements related to long-term intercompany loans are recognized in other comprehensive income.

Foreign currency exchange transaction gain (loss) is the result of re-measuring transactions denominated in a currency other than the functional currency of the entity recording the transaction.

Restricted Cash

As of March 31, 2016 and December 31, 2015, the Company's restricted cash is in connection with the patent and utility model infringement proceedings against TauroPharm (see Note 5). The Company was required by the District Court Mannheim to provide a security deposit of approximately $132,000–––––––––––––––––– to cover legal fees in the event TauroPharm is entitled to reimbursement of these costs. The Company furthermore had to provide a deposit in the amount of $40,000 in connection with the unfair competition proceedings in Cologne.

Prepaid Research and Development and Other Prepaid Expenses

Prepaid expenses consist of payments made in advance to vendors relating to service contracts for clinical trial development, manufacturing, preclinical development and insurance policies. These advanced payments are amortized to expense either as services are performed or over the relevant service period using the straight-line method.

Inventories, net

Inventories are valued at the lower of cost or market on a first in, first out basis. Inventories consist of raw materials (including labeling and packaging), work-in-process, and finished goods, if any, for the Neutrolin product. Inventories consist of the following:

| | March 31, 2016 | December 31, 2015 |
|---|---|---|
| Raw materials | $244,386 | $244,459 |
| Work in process | 400,361 | 424,622 |
| Finished goods | 11,554 | 7,488 |
| Inventory reserve | (322,428) | (300,000) |
| Total | $333,873 | $376,569 |

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CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Accrued Expenses

Accrued expenses consist of the following:

| | March 31, 2016 | December 31, 2015 |
|---|---|---|
| Professional and consulting fees | $392,774 | $282,975 |
| Accrued payroll and payroll taxes | 567,900 | 532,084 |
| Clinical Trial and manufacturing development | 255,951 | 226,042 |
| Market research | - | 3,225 |
| Monitoring program fees | 46,908 | 65,076 |
| Statutory taxes | 70,805 | 67,236 |
| Other | 12,587 | 44,919 |
| Total | $1,346,925 | $1,221,557 |

Revenue Recognition

The Company recognizes revenue in accordance with SEC Staff Accounting Bulletin (“SAB”) No. 101, Revenue Recognition in Financial Statements (“SAB 101”), as amended by SAB No. 104, Revenue Recognition (“SAB 104”) and Financial Accounting Standard Board (“FASB”) Accounting Standards Codification (“ASC”) 605, Revenue Recognition (“ASC 605”). This guidance requires that revenue is recognized from product sales when the following four revenue recognition criteria are met: persuasive evidence of an arrangement exists, delivery has occurred, the selling price is fixed or determinable, and collectability is reasonably assured. The Company recognizes net sales upon shipment of product to the dialysis centers.

Deferred Revenue

In October 2015, the Company shipped product with less than 75% of its remaining shelf life to a customer and issued a guarantee that the specific product shipped would be replaced by the Company if the customer was not able to sell the product before it expired. As a result of this warranty, the Company may have an additional performance obligation (i.e. accept returned product and deliver new product to the customer) if the customer is unable to sell the short-dated product. Due to limited sales experience with the customer, the Company is unable to estimate the amount of the warranty obligation that may be incurred as a result of this shipment. Therefore, the Company has deferred the revenue and related cost of sales associated with the shipment of this product. Since the Company will be unable to resell the expired product if returned by the customer, the deferred revenue and related cost of sales is presented net as Deferred Revenue on the condensed consolidated balance sheet which amounted to $126,000 and $121,000 at March 31, 2016 and December 31, 2015, respectively.

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

In August 2014, the Company entered into an exclusive distribution agreement (the "Wonik Agreement") with Wonik Corporation, a South Korean company, to market, sell and distribute Neutrolin for hemodialysis and oncolytic patients upon receipt of regulatory approval in Korea. Upon execution of the Wonik Agreement, Wonik paid the Company a non-refundable $50,000 payment and will pay an additional $50,000 upon receipt of the product registration necessary to sell Neutrolin in the Republic of Korea (the "Territory"). The term of the Wonik Agreement commenced on August 8, 2014 and will continue for three years after the first commercial sale of Neutrolin in the Territory. The non-refundable up-front payment has been recorded as deferred revenue and will be recognized as revenue on a straight-line basis over the contractual term of the Agreement. The Company recognized $2,200 revenue related to the Wonik agreement for each of the three months ended March 31, 2016 and 2015. Deferred revenue balance at March 31, 2016 and December 31, 2015 amounted to $9,000 for each period and deferred revenue long-term balances at March 31, 2016 and December 31, 2015 amounted to $27,000 and $29,000, respectively.

Loss per common share

Basic loss per common share excludes any potential dilution and is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per common share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that then shared in the earnings of the entity. However, since their effect is anti-dilutive, the Company has excluded potentially dilutive shares. The following potentially dilutive shares have been excluded from the calculation of diluted net loss per share as their effect would be anti-dilutive.

| | Three Months Ended | |
|---|---|---|
| | March 31, 2016 | March 31, 2015 |
| Series C non-voting convertible preferred stock | 2,865,000 | 2,865,000 |
| Series D non-voting convertible preferred stock | 1,479,240 | 1,479,240 |
| Series E non-voting convertible preferred stock | 1,959,759 | 1,959,759 |
| Shares underlying outstanding warrants | 4,031,468 | 6,890,327 |
| Shares underlying outstanding stock options | 4,483,545 | 4,014,500 |
| Total | 14,819,012 | 17,208,826 |

Stock-Based Compensation

The Company accounts for stock options granted to employees, officers and directors according to ASC No. 718, "Compensation — Stock Compensation" ("ASC 718"). Share-based compensation cost is measured at grant date, based on the estimated fair value of the award using the Black-Scholes option pricing model, and is recognized as expense net of expected forfeitures, over the employee's requisite service period on a straight-line basis.

The Company accounts for stock options granted to non-employees on a fair value basis using the Black-Scholes option pricing model in accordance with ASC 718 and ASC No. 505-50, "Equity-Based Payments to Non-Employees" ("ASC 505"). The non-cash charge to operations for non-employee options with time based vesting provisions is based on the fair value of the options re-measured each reporting period and amortized to expense over the related vesting period. The non-cash charge to operations for non-employee options with performance based vesting provisions is recorded when the achievement of the performance condition is probable.

Stock compensation expense is recognized by applying the expected forfeiture rate during the vesting period to the fair value of the award. The estimation of the number of stock awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from the Company's current estimates, compensation expense may need to be revised. The Company considers many factors when estimating expected forfeitures for stock awards granted to employees, officers and directors, including types of awards, employee class, and an analysis of historical forfeitures.

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Research and Development

Research and development costs are charged to expense as incurred. Research and development includes fees associated with operational consultants, contract clinical research organizations, contract manufacturing organizations, clinical site fees, contract laboratory research organizations, contract central testing laboratories, licensing activities, and allocated executive, human resources and facilities expenses. The Company accrues for costs incurred as the services are being provided by monitoring the status of the trial and the invoices received from its external service providers. As actual costs become known, the Company adjusts its accruals in the period when actual costs become known. Costs related to the acquisition of technology rights and patents for which development work is still in process are charged to operations as incurred and considered a component of research and development expense.

Note 3 — Stockholders' Equity:

Common Stock

The Company has At-the-Market Issuance Sales Agreement (the "Sales Agreement") with MLV & Co. LLC, now a subsidiary of FBR & Co., ("MLV") under which the Company may issue and sell up to $40.0 million of shares of its common stock from time to time through MLV acting as agent, subject to limitations imposed by the Company, such as the number or dollar amount of shares registered under the registration statement to which the offering relates. When the Company wishes to issue and sell common stock under the Sales Agreement, it notifies MLV of the number of shares to be issued, the dates on which such sales are anticipated to be made, any minimum price below which sales may not be made and other sales parameters as the Company deems appropriate. MLV is entitled to a commission of up to 3% of the gross proceeds from the sale of common stock sold under the Sales Agreement. The shares of common stock to be sold under the Sales Agreement are registered under an effective registration statement filed with the SEC. During the quarter ended March 31, 2016, the Company issued 74,975 shares of common stock under the Sales Agreement and realized net proceeds of approximately $149,276.

During the quarter ended March 31, 2016, the Company issued the following shares of its common stock upon exercise of stock options resulting in gross proceeds of $116,700 to the Company:

- 30,000 shares of common stock with an exercise price of $0.29 per share;
- 20,000 shares of common stock with an exercise price of $0.90 per share; and
- 50,000 shares of common stock with an exercise price of $1.80 per share.

Stock Options

During the three months ended March 31, 2016, the Company granted ten-year non-qualified stock options under the 2013 Plan covering an aggregate of 990,000 shares of the Company's common stock to its officers, directors, employees and consultants.

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During the three months ended March 31, 2016 and 2015, total compensation expense for stock options issued to employees, directors, officers and consultants was $442,069 and $1,026,924, respectively.

The fair value of the grants are determined using the Black-Scholes option pricing model with the following assumptions:

| | Three Months Ended March 31, 2016 |
|---|---|
| Expected Term | 5 – 10 years |
| Volatility | 96 % |
| Dividend yield | 0.0 % |
| Risk-free interest rate | 1.25% - 1.94 % |

The Company estimated the expected term of the stock options granted based on anticipated exercises in future periods. The expected term of the stock options granted to consultants is based upon the full term of the respective option agreements. The expected stock price volatility for the Company's stock options is calculated based on the historical volatility since the initial public offering of the Company's common stock in March 2010. The expected dividend yield of 0.0% reflects the Company's current and expected future policy for dividends on the Company's common stock. To determine the risk-free interest rate, the Company utilized the U.S. Treasury yield curve in effect at the time of grant with a term consistent with the expected term of the Company's awards.

A summary of the Company's stock option activity and related information for the three months ended March 31, 2016 is as follows:

| | Shares | Weighted Average Exercise Price |
|---|---|---|
| Outstanding at beginning of period | 3,600,045 | $1.82 |
| Exercised | (100,000 ) | $1.17 |
| Forfeited | (6,500 ) | $4.78 |
| Expired | - | - |
| Granted | 990,000 | $2.03 |
| Outstanding at end of period | 4,483,545 | $1.88 |
| Options exercisable | 3,352,947 | $1.78 |
| Weighted-average fair value of options granted during the period | | $1.56 |
| | | |
| Weighted average remaining contractual life of stock options outstanding (years) | | 8.0 |
| Weighted average remaining contractual life of stock options exercisable (years) | | 7.4 |
| Weighted average vesting period over which total compensation expense related to non-vested options not yet recognized (years) | | 1.2 |

| | |
|---|---|
| Compensation expense related to non-vested options not yet recognized | $1,646,036 |
| Aggregate intrinsic value of stock options exercised | $77,600 |
| Aggregate intrinsic value of stock options outstanding | $4,663,769 |

The aggregate intrinsic value is calculated as the difference between the exercise prices of the underlying options and the quoted closing price of the common stock of the Company at the end of the reporting period for those options that have an exercise price below the quoted closing price.

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Warrants

The following table is the summary of warrant activity for the three months ended March 31, 2016:

| | Shares | Weighted Average Exercise Price | Weighted Average Remaining Contractual Life |
|---|---|---|---|
| Outstanding at beginning of period | 4,422,188 | $1.80 | 3.07 |
| Granted | - | - | - |
| Expired | (390,720 ) | $3.44 | - |
| Exercised | - | | |
| Outstanding at end of period | 4,031,468 | $1.64 | 3.10 |

Note 4 — Related Party Transactions:

On March 3, 2015, the Company entered into a backstop agreement with an existing institutional investor, Manchester Securities Corp., a wholly owned subsidiary of Elliott Associates, L.P., and a beneficial holder of more than 5% of the Company's outstanding common stock. Pursuant to the backstop agreement, Manchester had agreed to lend the Company, at its request, up to $4,500,000 less the dollar amount of gross proceeds received by the Company upon the exercise of warrants to purchase common stock issued in connection with its IPO on or before April 30, 2015, provided that the loan could not exceed $3,000,000. The backstop agreement was not accessed. Pursuant to the backstop agreement, the Company granted Manchester the right for as long as it or its affiliates hold any of the Company's common stock or securities convertible into its common stock the right to appoint up to two members to the Company's board of directors and/or to have up to two observers attend board meetings in a non-voting capacity. Manchester appointed one director in August 2015 and appointed another director in April 2016.

Note 5 — Commitments and Contingencies:

Contingency Matters

On September 9, 2014, the Company filed in the District Court of Mannheim, Germany a patent infringement action against TauroPharm GmbH and Tauro-Implant GmbH as well as their respective CEOs (the "Defendants") claiming infringement of the Company's European Patent EP 1 814 562 B1, which was granted by the EPO on January 8, 2014 (the "Prosl European Patent"). The Prosl European Patent covers a low dose heparin catheter lock solution for maintaining patency and preventing infection in a hemodialysis catheter. In this action, the Company claims that the Defendants infringe on the Prosl European Patent by manufacturing and distributing catheter locking solutions to the extent they are covered by the claims of the Prosl European Patent. The Company believes that its patent is sound, and is seeking injunctive relief and raising claims for information, rendering of accounts, calling back, destruction and damages. Separately, TauroPharm has filed an opposition with the EPO against the Prosl European Patent alleging that it lacks novelty and inventive step. The Company cannot predict what other defenses the Defendants may raise, or the ultimate outcome of either of these related matters.

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In the same complaint against the same Defendants, the Company also alleged an infringement (requesting the same remedies) of NDP's utility model DE 20 2005 022 124 U1 (the "Utility Model"), which the Company believes is fundamentally identical to the Prosl European Patent in its main aspects and claims. The Court separated the two proceedings and the Prosl European Patent and the Utility Model claims are now being tried separately. TauroPharm has filed a cancellation action against the Utility Model before the German Patent and Trademark Office based on the similar arguments as those in the opposition against the Prosl European Patent.

On March 27, 2015, the District Court held a hearing to evaluate whether the Utility Model has been infringed by TauroPharm in connection with the manufacture, sale and distribution of its TauroLock-HEP100TM and TauroLock-HEP500TM products. A hearing before the same court was held on January 30, 2015 on the separate, but related, question of infringement of the Prosl European Patent by TauroPharm.

The Court issued its decisions on May 8, 2015 staying both proceedings. In its decisions, the Court found that the commercialization by TauroPharm in Germany of its TauroLock catheter lock solutions Hep100 and Hep500 infringes both the Prosl European Patent and the Utility Model and further that there is no prior use right that would allow TauroPharm to continue to make, use or sell its product in Germany. However, the Court declined to issue an injunction in favor of the Company that would preclude the continued commercialization by TauroPharm based upon its finding that there is a sufficient likelihood that the EPO, in the case of the Prosl European Patent, or the German Patent and Trademark Office (the "German PTO"), in the case of the Utility Model, may find that such patent or utility model is invalid. Specifically, the Court noted the possible publication of certain instructions for product use that may be deemed to constitute prior art. As such, the District Court determined that it will defer any consideration of the request by the Company for injunctive and other relief until such time as the EPO or the German PTO has ruled on the underlying validity of the Prosl European Patent and the Utility Model.

Both the opposition proceedings against the Prosl European Patent before the EPO and the cancellation action against the Utility Model before the German PTO are ongoing. The EPO held a hearing in the opposition proceeding on November 25, 2015. In its preliminary consideration of the matter, the EPO (and the German Patent and Trademark Office) had regarded the patent as not inventive or novel due to publication of prior art. However, the EPO did not issue a decision at the end of the hearing but adjourned the matter due to the fact that the panel was of the view that Claus Herdeis, one of the managing directors of TauroPharm, has to be heard as a witness in a further hearing in order to close some gaps in the documentation presented by TauroPharm as regards the publication of the prior art. No date has yet been scheduled for such hearing. While the Company continues to believe that the referenced publication and instructions for use do not, in fact, constitute prior art and that the Prosl European Patent and the Utility Model validly claim inventions that will be found to be such by the EPO and the German PTO, there can be no assurance that the Company will prevail in this matter. The German PTO has scheduled a hearing for May 11, 2016 which has, however, been rescheduled to June 29, 2016 due to conflicting court appointments of some members of the legal team. The Company therefore does not expect a decision from the German PTO in the Utility Model matter before mid-2016, with any such decision also being subject to appeal.

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On January 16, 2015, the Company filed a complaint against TauroPharm GmbH and its managing directors in the District Court of Cologne, Germany. In the complaint, the Company alleges violation of the German Unfair Competition Act by TauroPharm for the unauthorized use of its proprietary information obtained in confidence by TauroPharm. The Company alleges that TauroPharm is improperly and unfairly using its proprietary information relating to the composition and manufacture of Neutrolin, in the manufacture and sale of TauroPharm's products TauroLockTM, TauroLock-HEP100 and TauroLock-HEP500. The Company seeks a cease and desist order against TauroPharm from continuing to manufacture and sell any product containing taurolidine (the active pharmaceutical ingredient ("API") of Neutrolin) and citric acid in addition to possible other components, damages for any sales in the past and the removal of all such products from the market. A hearing in this matter was scheduled for July 2, 2015, but was postponed by the Court to November 19, 2015. In this hearing, the presiding judge explained that the court needed more information with regard to several aspects of the case. As a consequence, the court issued an interim decision in the form of a court order outlining several issues of concern that relate primarily to court's interest in clarifying the facts and reviewing any and all available documentation, in particular with regard to the question which specific know-how was provided to TauroPharm by whom and when. The Company's legal team has prepared the requested reply and produced the respective documentation. TauroPharm has also filed another writ to which the Company will have to reply by the end of April. A date for a further oral hearing has not been scheduled yet.

In connection with the aforementioned patent and utility model infringement proceedings against TauroPharm, the Company was required by the District Court Mannheim to provide a security deposit of approximately $132,000−−−−−−−−−−−−−−−−− to cover legal fees in the event TauroPharm is entitled to reimbursement of these costs. The Company recorded the deposit as restricted cash for the year ended December 31, 2015. The Company furthermore had to provide a deposit in the amount of $40,000 in connection with the unfair competition proceedings in Cologne.

On July 7, 2015, a putative class action lawsuit was commenced against the Company and certain of its current and former officers in the United States District Court for the District of New Jersey, captioned Li v. Cormedix Inc., et al., Case 3:15-cv-05264. On September 4, 2015, two individuals, Shahm Martini and Paul Chretien (the "Martini Group"), filed a Motion to Appoint Lead Plaintiff. On that same date, another individual, Elaine Wood, filed a competing Motion to Appoint Lead Plaintiff. On September 18, 2015, the Martini Group withdrew its motion. Thereafter, on September 22, 2015, the Court appointed Elaine Wood as Lead Plaintiff and, on October 2, 2015, appointed the Rosen Law Firm as Lead Counsel.

On December 1, 2015, Lead Plaintiff filed an Amended Complaint asserting claims that the Company and Steven Lefkowitz, Randy Milby and Harry O'Grady (the "Cormedix Defendants") violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder and Section 20(a) of the Exchange Act. The Amended Complaint also names as defendants several unrelated entities that allegedly were paid stock promoters. Lead Plaintiff alleges generally that the Cormedix Defendants made materially false or misleading statements and omissions concerning, among other things, the competitive landscape for the Company's Neutrolin product and the alleged use of stock promoters. The Amended Complaint seeks unspecified damages, interest, attorneys' fees, and other costs.

On February 1, 2016, the Cormedix Defendants filed a motion to dismiss all claims asserted against them in the Amended Complaint on the grounds, among others, that the Amended Complaint fails to adequately allege: (1) material misstatements or omissions; (2) scienter by any of the Cormedix Defendants; or (3) loss causation. The parties are in the process of briefing that motion and oral argument currently is scheduled for July 18, 2016. The Company believes that it has substantial legal and factual defenses to the claims in the class action and intends to continue vigorously defending the case.

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Commitments

Manufacturing

Navinta LLC, a U.S.-based API developer, provides API manufacturing (manufactured in India at an FDA-compliant facility) and a Drug Master File for CRMD003, pursuant to an original supply agreement dated December 7, 2009 (the "Navinta Agreement"). The Navinta Agreement provided that Navinta will supply taurolidine (the API for CRMD003) to the Company on an exclusive worldwide basis in the field of the prevention and treatment of human infection and/or dialysis so long as the Company purchases a minimum of $2,250,000 of product on an annual basis for five years following the Company's first commercial sale of a product incorporating taurolidine. The Company did not purchase the required amounts and as a result, lost its exclusive manufacturing rights. The Company is also required to make certain cash payments to Navinta upon the achievement of certain sales-based milestones which is based on a tiered approach and does not commence until the Company achieves a designated net sales threshold. The maximum aggregate amount of such payments, assuming achievement of all milestones, is $1,975,000 over five years. There were no milestones achieved during the three months ended March 31, 2016.

On March 24, 2015, the Company and Navinta LLC entered into an amendment to the Navinta Agreement to extend the term of the Navinta Agreement to March 31, 2016 and to lower the price per kilogram of API that the Company purchases from Navinta LLC under the Navinta Agreement. The Company also agreed to purchase a minimum amount of product from Navinta LLC during 2015, which replaced the prior minimum purchase requirement. The Navinta Agreement may be terminated by either party upon 30 days written notice. The Navinta Agreement expired in accordance with its terms upon the delivery of API in the second quarter of 2016.

The Company announced a program aimed at reducing the cost of goods of Neutrolin through a more efficient, custom synthesis of the active ingredient taurolidine. As part of that program, on April 8, 2015, the Company entered into a Preliminary Services Agreement with [RC]2 Pharma Connect LLC ("RC2"), pursuant to which RC2 will coordinate certain manufacturing services related to taurolidine. Specifically, RC2 will undertake a critical parameters evaluation for the Company's manufacturing needs and coordinate the cGMP processes set forth in the agreement that the Company believes are necessary for the submission of its planned new drug application for Neutrolin to the FDA, as well as any foreign regulatory applications. The total cost for RC2's services under the preliminary services agreement is expected to be approximately $1.7 million which is expected to be incurred through the third quarter of 2016. During the three months ended March 31, 2016, the Company recognized research and development expense of $38,000 for its services related to the agreement.

The Company is also working with RC2 under several service agreements for the manufacture of clinical supplies to support its ongoing and planned Phase 3 clinical trials for an aggregate amount of $3 million. During the three months ended March 31, 2016, the Company recognized research and development expense of approximately $420,000 related to these agreements. The Company may terminate these agreements upon 30 days written notice and is only obligated for project costs and reasonable project shut down costs provided through the date of termination.

Clinical and Regulatory

In December 2015, CorMedix signed a Master Service Agreement and Work Order (the "Master Service Agreement") with PPD Development, LP ("PPD") for a $19.2 million Phase 3 multicenter, double-blind, randomized active control study (the "Phase 3 Clinical Trial") to demonstrate the safety and effectiveness of Neutrolin in preventing

catheter-related bloodstream infections and blood clotting in subjects receiving hemodialysis therapy as treatment for end stage renal disease. The Phase 3 Clinical Trial is expected to run for 18 months and accrue up to 632 patients in 70 sites in the US. The Phase 3 Clinical Trial will stop when there are 162 incidences and an interim analysis will be performed after 81 incidences to determine whether additional sites and patients are required to complete the study. Prior to the signing of the Master Service Agreement, CorMedix signed a Letter of Agreement ("LOA") with PPD in July 2015. The original LOA was subsequently amended later in July 2015 for a total of $2.75 million, to revise and expand the scope of services provided by PPD in connection with the identification, activation and management of 70 U.S. sites for the Phase 3 Clinical Trial described above. When the Master Service Agreement was signed in December 2015, the amended LOA was rolled into the $19.2 million Phase 3 Clinical Trial. During the three months ended March 31, 2016, the Company recognized $900,000 research and development expense related to this agreement.

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In-Licensing

In 2008, the Company entered into a License and Assignment Agreement (the "NDP License Agreement") with NDP. Pursuant to the NDP License Agreement, NDP granted the Company exclusive, worldwide licenses for certain antimicrobial catheter lock solutions, processes for treating and inhibiting infections, a biocidal lock system and a taurolidine delivery apparatus, and the corresponding United States and foreign patents and applications (the "NDP Technology"). The Company acquired such licenses and patents through its assignment and assumption of NDP's rights under certain separate license agreements by and between NDP and Dr. Hans-Dietrich Polaschegg, Dr. Klaus Sodemann and Dr. Johannes Reinmueller. As consideration in part for the rights to the NDP Technology, the Company paid NDP an initial licensing fee of $325,000 and granted NDP a 5% equity interest in the Company, consisting of 39,980 shares of the Company's common stock.

In addition, the Company is required to make payments to NDP upon the achievement of certain regulatory and sales-based milestones. Certain of the milestone payments are to be made in the form of shares of common stock currently held in escrow for NDP, and other milestone payments are to be paid in cash. The maximum aggregate number of shares issuable upon achievement of milestones is 145,543 shares. In 2014, a certain milestone was achieved resulting in the release of 36,386 shares held in escrow. The number of shares held in escrow as of March 31, 2016 is 109,157 shares of common stock. The maximum aggregate amount of cash payments upon achievement of milestones is $3,000,000 with $2,500,000 remaining at March 31, 2016. Events that trigger milestone payments include but are not limited to the reaching of various stages of regulatory approval and upon achieving certain worldwide net sales amounts. There were no milestones achieved during the three months ended March 31, 2016.

The NDP License Agreement may be terminated by the Company on a country-by-country basis upon 60 days prior written notice. If the NDP License Agreement is terminated by either party, the Company's rights to the NDP Technology will revert back to NDP.

Other

On August 3, 2015, the Company entered into a Release of Claims and Severance Modification with Randy Milby, its Chief Executive Officer, due to the anticipated termination of Mr. Milby's employment. In exchange for the release of various claims by Mr. Milby against the Company, including claims related to his employment with Company and the termination of same and claims for additional compensation or benefits other than the compensation and benefits set forth in his employment agreement, the Company agreed to amend Mr. Milby's employment agreement, dated as of March 31, 2014, to specify that Mr. Milby may not compete against the Company by engaging in any business involving the development or commercialization of (i) a preventive anti-infective product that would be a direct competitor of Neutrolin or (ii) a product containing taurolidine. The non-compete term did not change and remains at twelve months following termination of his employment. The employment agreement was also amended to allow Mr. Milby a period in which to exercise all vested options and warrants until the later of 60 months following the termination date of his employment or 60 months following the date on which his service on the Company's Board of Directors ends, provided in no event shall he be able to exercise after the respective expiration date of any stock option or warrant. During the year ended December 31, 2015, the Company recorded non-cash expense of $507,341 as a result of this modification.

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Pursuant to the terms of his employment agreement, Mr. Milby will be entitled to receive his base salary and benefits for a period of twelve months following the effective date of the termination of his employment, or, in the case of benefits, until such time as he receives equivalent coverage and benefits under plans and programs of a subsequent employer if such receipt is prior to the expiration of the twelve month period. To the extent any of the aforementioned benefits cannot be provided to former employees, the Company will pay Mr. Milby a lump-sum payment in the amount necessary to allow Mr. Milby to purchase the equivalent benefits. The Company accrued $325,000 of severance pay during the year ended December 31, 2015 which remained unpaid at March 31, 2016.

The Company entered into sublease for 4,700 square feet of office space in Bedminster, New Jersey, which sublease runs from April 1, 2015 until March 31, 2018. Rent is $5,000 per month plus occupancy costs such as utilities, maintenance and taxes. In accordance with the lease agreement, the Company has deposited $5,000 with the landlord, the equivalent of one month rent.

The Company's subsidiary entered into a lease agreement for its offices in Fulda, Germany with ITZ GmbH. The lease has a term of 36 months which commenced on September 1, 2013 for a base monthly payment of €498. The total 36 month lease obligation is approximately €17,900 ($20,000).

Rent expense for the three months ended March 31, 2016 and 2015, was $17,000 and $23,000, respectively.

Under the Company's current lease agreements, the total remaining lease obligation as of March 31, 2016 is set forth below:

| | |
|---|---|
| 2016 | $63,705 |
| 2017 | 60,549 |
| Total | $124,254 |

Note 6 — Concentrations:

At March 31, 2016 and December 31, 2015, approximately 89% and 93% of net accounts receivable, respectively, was due from one customer.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our 2015 Annual Report on Form 10-K, filed with the Securities and Exchange Commission, or the SEC, on March 15, 2016.

Forward Looking Statements

This Quarterly Report on Form 10-Q contains "forward-looking statements" that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. The statements contained in this Quarterly Report on Form 10-Q that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended or the Exchange Act. Forward-looking statements are often identified by the use of words such as, but not limited to, "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "intend," "may," "will," "plan," "project," "seek," "sh "would," and similar expressions or variations intended to identify forward-looking statements. These statements are based on the beliefs and assumptions of our management based on information currently available to management. Such forward-looking statements are subject to risks, uncertainties and other important factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled "Risk Factors" included in our most recent annual report on Form 10-K, as well as any amendments thereto, as filed with the SEC and which are incorporated herein by reference. Furthermore, such forward-looking statements speak only as of the date of this report. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

Overview

CorMedix Inc. and Subsidiary (referred to herein as "we," "us," "our" and the "Company"), is a commercial pharmaceutical and medical device company. We in-license, develop and commercialize prophylactic and therapeutic products for the prevention and treatment of infectious and inflammatory diseases. We have in-licensed the worldwide rights to develop and commercialize our product CRMD003 (Neutrolin®), which we believe addresses potentially large market opportunities in the instances in which a central venous catheter is used, such as hemodialysis, intensive care units, oncology and total parenteral nutrition, IV hydration, and/or IV medications.

Neutrolin is an anti-infective solution for the prevention of catheter-related infections and thrombosis in the central venous catheter markets such as dialysis, critical care, and oncology. Catheter related blood stream infections cause extensive morbidity and mortality, prolonged hospital stays and cost the U.S. healthcare system over $11 billion per year. Neutrolin is a novel formulation of taurolidine, citrate and heparin 1000 u/ml that provides a combination preventative solution to decrease the development of biofilm in order to reduce infection and thrombosis and thereby keep catheters operating optimally in clinical settings in hemodialysis, critical care/intensive care and oncology. Our initial target market for Neutrolin was hemodialysis using a tunneled central vein catheter, and we launched Neutrolin as a medical device in our first geographical market, Germany, in December 2013.

In July 2013, we received CE Mark approval for Neutrolin. As a result, in December 2013, we began the commercial launch of Neutrolin in Germany for the prevention of catheter-related bloodstream infections ("CRBSI"), and maintenance of catheter patency in hemodialysis patients using a tunneled, cuffed central venous catheter for vascular access. To date, Neutrolin is registered and may be sold in Austria, Germany, Italy, Malta, Saudi Arabia, Bahrain, Qatar, Kuwait, United Arab Emirates and The Netherlands for such treatment.

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In September 2014, the TUV-SUD and The Medicines Evaluation Board of the Netherlands granted a label expansion for Neutrolin for these same expanded indications for the European Union ("EU"). In December 2014, we received approval from the Hessian District President in Germany to expand the label to include use in oncology patients receiving chemotherapy, IV hydration and IV medications via central venous catheters. The expansion also adds patients receiving medication and IV fluids via central venous catheters in intensive or critical care units (cardiac care unit, surgical care unit, neonatal critical care unit, and urgent care centers). An indication for use in total parenteral nutrition was also approved.

In late 2013, we met with the U.S. Food and Drug Administration (the "FDA") to determine the pathway for U.S. approval of Neutrolin. Based on our discussions with the FDA, we plan to conduct at least one Phase 3 clinical trial in hemodialysis catheters, which began in December 2015, and one Phase 3 clinical trial in oncology/total parenteral nutrition. We have worked with the FDA to design the protocol for a planned Phase 3 clinical trial in hemodialysis patients with a central venous catheter; this protocol was accepted in August 2014 and we filed an investigational new drug application ("IND") in September 2014. In October 2014, the FDA informed us that it had determined that the IND is not subject to a clinical hold, and the Phase 3 clinical trial in hemodialysis patients was initiated in the U.S. in December 2015.

In June 2015, we received guidance from the FDA on the acceptable design of the second planned pivotal Phase 3 trial in oncology/total parenteral nutrition patients and are working with the FDA to finalize the details. We plan to initiate the Phase 3 trial in oncology/total parenteral nutrition in the first quarter of 2017, depending on our ability to raise additional capital and our ability to complete the hemodialysis catheters trial within our expected budget, although we also plan to continue to seek one or more strategic partners or other sources of capital to complete the development of Neutrolin in the U.S.

We are evaluating opportunities for the possible expansion of indications for taurolidine. Provisional patents have been submitted in four areas, antimicrobial sutures, nanofiber webs, wound management, and osteoarthritis and visco-supplementation. There exists a need to control and protect against surgical site infections upon closure with sutures. We believe taurolidine could offer benefits not currently available in marketed antimicrobial sutures. We also believe that the nanofiber webs used for absorbable meshes could benefit from taurolidine's minimal inflammatory response and infection control. Taurolidine incorporated into webs or hydrogels could also be used for wound management especially wounds in less sterile environments and burn patients. Lastly, incorporating taurolidine into formulations for osteoarthritis and visco-supplementation may benefit from taurolidine's anti-inflammatory and anti-infection properties.

In March 2015, we commenced a process to evaluate our strategic alternatives in order to accelerate the global development of Neutrolin and maximize shareholder value. We engaged investment bank Evercore Group L.L.C. to provide financial advice and assist us with our evaluation process. After the process with Evercore, we announced in July 2015 that we expect to continue to pursue product development and commercialization opportunities as we move forward with the planned Phase 3 clinical trials, rather than pursuing a possible sale of our company as this time. We continue to retain Evercore and will work with them as potential opportunities are presented to us.

Since our inception, we have not generated enough revenue from product sales to be profitable. Our operations to date have been primarily limited to licensing product candidates, developing clinical trials for our product candidates, establishing manufacturing for our product candidates, performing business and financial planning, performing research and development, seeking regulatory approval for our products, initial commercialization activities for Neutrolin, and maintaining and improving our patent portfolio. We have funded our operations primarily with debt and equity financings. We have generated significant losses to date, and we expect to incur increases in our cash used in operations as we continue to market Neutrolin in Europe and other markets, prepare for and undertake our ongoing and planned Phase 3 clinical trials, pursue business development activities, incur additional legal costs to defend our

intellectual property, and seek FDA approval of Neutrolin in the U.S. As of March 31, 2016, we had an accumulated deficit of approximately $98.6 million. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

Financial Operations Overview

Revenue

We recognize revenue in accordance with SEC Staff Accounting Bulletin (SAB) No. 101, Revenue Recognition in Financial Statements (SAB 101), as amended by SAB No. 104, Revenue Recognition (SAB 104) and Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 605, Revenue Recognition (ASC 605).

Our product shipments to dialysis centers began in December 2013. Orders are processed through a distributor. The distributor remits payment to us upon collection from the customer. We recognize net sales upon shipment of product to the dialysis centers.

Deferred Revenue

In August 2014, we entered into an exclusive distribution agreement (the "Agreement") with Wonik Corporation, a South Korean company, to market, sell and distribute Neutrolin for hemodialysis and oncolytic patients upon receipt of regulatory approval in Korea. Upon execution of the Agreement, Wonik paid us a non-refundable $50,000 payment and will pay an additional $50,000 upon receipt of the product registration necessary to sell Neutrolin in the Republic of Korea (the "Territory"). The term of the agreement commenced on August 8, 2014 and will continue for three years after the first commercial sale of Neutrolin in the Territory. The non-refundable up-front payment has been recorded as deferred revenue and will be recognized as revenue on a straight-line basis over the contractual term of the Agreement.

In October 2015, we shipped product with less than 75% of its remaining shelf life to a customer and issued a guarantee that the specific product shipped would be replaced by us if the customer was not able to sell the product before it expired. As a result of this warranty, we may have an additional performance obligation (i.e. accept returned product and deliver new product to the customer) if the customer is unable to sell the short-dated product. Due to limited sales experience with the customer, we are unable to estimate the amount of the warranty obligation that may be incurred as a result of this shipment. Therefore, we deferred the revenue and related cost of sales associated with the shipment of this product. Since we will be unable to resell the expired product if returned by the customer, the deferred revenue and related cost of sales is presented net as Deferred Revenue on the condensed consolidated balance sheet.

Research and Development Expense

Research and development, or R&D, expense consists of: (i) internal costs associated with our development activities; (ii) payments we make to third party contract research organizations, contract manufacturers, investigative sites, and consultants; (iii) technology and intellectual property license costs; (iv) manufacturing development costs; (v) personnel related expenses, including salaries, stock–based compensation expense, benefits, travel and related costs for the personnel involved in drug development; (vi) activities relating to regulatory filings and the advancement of our product candidates through preclinical studies and clinical trials; and (vii) facilities and other allocated expenses, which include direct and allocated expenses for rent, facility maintenance, as well as laboratory and other supplies. All R&D is expensed as incurred.

Conducting a significant amount of development is central to our business model. Product candidates in later-stage clinical development generally have higher development costs than those in earlier stages of development, primarily due to the significantly increased size and duration of the clinical trials. We plan to increase our R&D expenses for the foreseeable future in order to complete development of Neutrolin in the U.S.

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The process of conducting pre-clinical studies and clinical trials necessary to obtain regulatory approval is costly and time consuming. The probability of success for each product candidate and clinical trial may be affected by a variety of factors, including, among others, the quality of the product candidate's early clinical data, investment in the program, competition, manufacturing capabilities and commercial viability. As a result of the uncertainties associated with clinical trial enrollments and the risks inherent in the development process, we are unable to determine the duration and completion costs of current or future clinical stages of our product candidates or when, or to what extent, we will generate revenues from the commercialization and sale of any of our product candidates.

Development timelines, probability of success and development costs vary widely. Our current focus is on clinical development efforts in the U.S. Based on our discussions with the FDA, we initiated the Phase 3 clinical trial in hemodialysis catheters in December 2015 and subject to finalization of the protocol, we plan to initiate the Phase 3 trial in oncology/total parenteral nutrition in the first quarter of 2017, depending on our ability to raise additional capital and our ability to complete the hemodialysis catheters trial within our expected budget. We expect that the ongoing Phase 3 trial for hemodialysis catheters will cost approximately $26 million to $30 million and will take 18 months to complete after initiation. We are still finalizing the details of the protocol for the planned second Phase 3 trial for oncology/total parenteral nutrition and are unable to provide a cost estimate at this time. We are seeking one or more strategic partners or other sources of capital to complete the development of Neutrolin in the U.S.

Selling, General and Administrative Expense

Selling, general and administrative, or SG&A, expense includes costs related to commercial personnel, medical education professionals, marketing and advertising, salaries and other related costs, including stock-based compensation expense, for persons serving in our executive, sales, finance and accounting functions. Other SG&A expense includes facility-related costs not included in R&D expense, promotional expenses, costs associated with industry and trade shows, and professional fees for legal services and accounting services. We expect that our SG&A expenses will increase due to marketing of our Neutrolin product in Europe and other markets in which it may be approved.

Foreign Currency Exchange Transaction Gain (Loss)

Foreign currency exchange transaction gain (loss) is the result of re-measuring transactions denominated in a currency other than our functional currency and is reported in the consolidated statement of operations as a separate line item within other income (expense). Foreign currency exchange transaction gain (loss) consists of foreign exchange transaction gains and losses on intercompany loans that are in place between our company, which is based in New Jersey and our German subsidiary. The intercompany loans outstanding are not expected to be repaid in the foreseeable future and unrealized foreign exchange movements related to long-term intercompany loans are recorded in other comprehensive income (loss).

Interest Income

Interest income consists of interest earned on our cash and cash equivalents.

Interest Expense

Interest expense consists of interest incurred on financing of expenses.

Results of Operations

Three months ended March 31, 2016 compared to three months ended March 31, 2015

The following is a tabular presentation of our consolidated operating results (in thousands):

| | For the Three Months Ended March 31, | | % of Change Increase (Decrease) |
|---|---|---|---|
| | 2016 | 2015 | |
| Revenue | $41 | $31 | 33 % |
| Cost of sales | (50) | (17) | 190 % |
| Gross profit (loss) | (9) | 14 | (163)% |
| Operating Expenses: | | | |
| Research and development | (2,089) | (1,235) | 69 % |
| Selling, general and administrative | (2,163) | (2,693) | (20)% |
| Total operating expenses | (4,252) | (3,928) | 8 % |
| Loss from operations | (4,261) | (3,914) | 9 % |
| Interest income | 32 | 1 | 5726 % |
| Foreign exchange transaction loss | (1) | (1) | - |
| Value of warrants issued in connection with backstop financing | - | (1,583) | (100)% |
| Interest expense | (1) | (1) | - |
| Net loss | (4,231) | (5,498) | (23)% |
| Other comprehensive income (loss) | 31 | 3 | 998 % |
| Comprehensive loss | $(4,200) | $(5,495) | (24)% |

Revenue. Revenue was $41,000 for the three months ended March 31, 2016 compared to $31,000 in the same period last year. The majority of the revenue is from sales of Neutrolin in Germany and Middle East markets. In addition, we realized $2,000 associated with the amortization of deferred revenue from a non-refundable payment received from a distribution agreement for the three month periods ended March 31, 2016 and 2015.

Cost of Sales. Cost of sales was approximately $50,000 for the three months ended March 31, 2016 compared to $17,000 in the same period last year, an increase of $33,000. The increase was primarily due to the charge of $23,000 for the reserve of raw materials expected to expire before utilization and an increase in direct cost of materials of $20,000 due to the use of new commercial batches as compared to the use of old previously expensed research and development batches last year. These increases were offset by decreases in ongoing stability studies and services performed in the management of manufacturing of $9,000.

Research and Development Expense. R&D expense was approximately $2,089,000 for the three months ended March 31, 2016, an increase of $854,000, from $1,235,000 for the three months ended March 31, 2015. The increase was primarily attributable to $981,000 expenses related to Phase 3 clinical trial in hemodialysis catheters in the U.S., higher costs to support the U.S. clinical trial drug supply consisting of manufacturing process development activities of $388,000, consulting fees pertaining mainly to regulatory activities of $101,000, and personnel costs of $61,000. These increases were offset by decreased pharmacoeconomics, and pricing and market research studies of $306,000 and non-cash stock based compensation of $372,000.

Selling, General and Administrative Expense. SG&A expense was $2,163,000 for the three months ended March 31, 2016, a decrease of $530,000 from $2,693,000 for the three months ended March 31, 2015. The decrease was attributable to decreases in costs related to business development activities of $170,000; decrease in selling costs related to commercialization of Neutrolin in the EU of $199,000; and a non-cash charge of $213,000 for stock-based compensation expense. These decreases, among others of lesser significance, were offset by an increase in legal fees due mainly to ongoing intellectual property and securities litigations, increased SEC and clinical activities of $89,000.

Interest Income. Interest income was $32,000 for the three months ended March 31, 2016 compared to $500 for the same period last year, an increase of $31,500. The increase was attributable to having higher average interest-bearing cash balances during the three months ended March 31, 2016 as compared to the same period last year.

Other Comprehensive Income (Loss). Unrealized foreign exchange movements related to long-term intercompany loans and the translation of the foreign affiliate financial statements to U.S. dollars and unrealized movements related to short-term investment are recorded in other comprehensive income totaling a $31,000 and $3,000 gain for the three months ended March 31, 2016 and 2015, respectively.

Liquidity and Capital Resources

Sources of Liquidity

We have not been profitable and have generated operating losses since we were incorporated in July 2006. During the quarter ended March 31, 2016, we received gross proceeds of $149,300 from the issuance of 74,975 shares of common stock under the at-the-market-issuance sales agreement and $116,700 from the following exercise of stock options:

- 30,000 shares of common stock with an exercise price of $0.29 per share;
- 20,000 shares of common stock with an exercise price of $0.90 per share; and
- 50,000 shares of common stock with an exercise price of $1.80 per share.

Net Cash Used in Operating Activities

Net cash used in operating activities was $5,451,000 for the three months ended March 31, 2016 as compared to approximately $2,348,000 for the same period last year. The net loss of $4,231,000 for the three months ended March 31, 2016 was lower than cash used in operating activities by $1,220,000. The difference is primarily attributable to an increase in prepaid expenses of $1,680,000, offset by non-cash stock-based compensation of $442,000. In comparison for the same period last year, the net loss of $5,498,000 was higher than cash used in operating activities by $3,149,000. The difference was primarily attributable to a non-cash charge for warrants issued in connection with the backstop agreement of $1,583,000, non-cash stock-based compensation of $1,027,000 and increases in accounts payable and accrued expenses of $546,000 and $197,000, respectively, partially offset by increases in restricted cash and prepaid expenses of $132,000 and $76,000, respectively.

Net Cash Used in Investing Activities

Cash used in investing activities for the three months ended March 31, 2016 was $6,548,000, attributable to the purchase of short-term investments as compared to $13,000 for the same period last year due to the purchase of software for our German subsidiary.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $266,000 for the three months ended March 31, 2016 as compared to $6,828,000 for the same period last year, a decrease of $6,562,000. During the three months ended March 31, 2016, we received net proceeds of $149,000 from the sale of our common stock in an at-the-market program and $117,000 from the exercise of stock options. In comparison, for the same period last year, we received net proceeds of approximately $6,702,000 from the exercise of warrants and $126,000 from the exercise of stock options.

Funding Requirements

Our total cash on hand and short-term investments as of March 31, 2016 was $30,229,000 excluding restricted cash of $172,000, compared to $35,386,000 at December 31, 2015. Because our business has not currently generated positive operating cash flow, we will need to raise additional capital before we exhaust our current cash resources in order to

continue to fund our research and development activities and our business development activities, as well as to fund operations generally. Our continued operations and completion of our ongoing Phase 3 clinical trial for Neutrolin in hemodialysis catheters in the U.S. which was initiated in December 2015 and is expected to take 18 months to complete will depend on whether we are able to raise sufficient additional funds through various potential sources, such as equity, debt financings, and/or strategic relationships. We also plan to conduct an oncology/total parenteral nutrition patient Phase 3 clinical trial in the U.S. for which additional funds over and above the funds needed for the hemodialysis Phase 3 clinical trial will be required to complete that study. However, we can provide no assurances that financing or strategic relationships will be available on acceptable terms, or at all.

We expect to continue to fund operations from cash on hand and through either capital raising sources as previously described, which may be dilutive to existing stockholders, or through generating revenues from the licensing of our products or strategic alliances. At March 31, 2016, we had approximately $10.4 million available for sale under our at-the market program, however, we may seek to sell additional equity or debt securities, obtain a bank credit facility, or enter into a corporate collaboration or licensing arrangement, but can provide no assurances that any such financing will be available on acceptable terms, or at all. Moreover, the incurrence of indebtedness in connection with a debt financing would result in increased fixed obligations and could also result in covenants that would restrict our operations. Raising additional funds through collaboration or licensing arrangements with third parties may require us to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or to grant licenses on terms that may not be favorable to us or our stockholders. Our actual cash requirements may vary materially from those now planned, however, because of a number of factors including any change in the focus and direction of our research and development programs, any acquisition or pursuit of development of new product candidates, competitive and technical advances, costs of commercializing any of our product candidates, and costs of filing, prosecuting, defending and enforcing any patent claims and any other intellectual property rights.

While we expect to grow product sales, we do not anticipate that we will generate significant product sales revenue in the foreseeable future. In the absence of such revenue, we would experience continuing operating cash flow deficits. We expect to incur increases in our cash used in operations as we continue to commercialize Neutrolin in Europe and other foreign markets, prepare for and undertake our ongoing and planned Phase 3 clinical trials, pursue business development activities, incur additional legal costs to defend our intellectual property and seek FDA approval of Neutrolin in the U.S.

Based on our cash resources at March 31, 2016, our expectations for sales of Neutrolin in the currently approved markets and the expected cost of the Phase 3 clinical trial in hemodialysis catheters in the U.S., we believe that our existing cash will be sufficient to fund our operations for at least the next twelve months following the balance sheet date. However, if we are unable to raise additional funds when needed, we may not be able to complete our ongoing and planned Phase 3 clinical trials or market our products and we could be required to delay, scale back or eliminate some or all of our research and development programs. Each of these alternatives would likely have a material adverse effect on our business.

Critical Accounting Policies

Our management’s discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. On an ongoing basis, we evaluate these estimates and judgments, including those described below. We base our estimates on our historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results and experiences may differ materially from these estimates.

While our significant accounting policies are more fully described in Note 2 to our financial statements included with this report, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our reported financial results and affect the more significant judgments and estimates that we use in the preparation of our financial statements.

Stock-Based Compensation

We account for stock options according to the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") No. 718, "Compensation — Stock Compensation" ("ASC 718"). Under ASC 718, share-based compensation cost is measured at grant date, based on the estimated fair value of the award, and is recognized as expense net of expected forfeitures, over the employee's requisite service period on a straight-line basis.

We account for stock options granted to non-employees on a fair value basis using the Black-Scholes option pricing model in accordance with ASC 718 and ASC No. 505-50, "Equity-Based Payments to Non-Employees" ("ASC 505"). For the purpose of valuing options and warrants granted to our directors, officers, employees and consultants, we use the Black-Scholes option pricing model. The non-cash charge to operations for non-employee options with time based vesting provisions is based on the fair value of the options re-measured each reporting period and amortized to expense over the related vesting period, and the non-cash charge to operations for non-employee options with performance based vesting provisions is recorded when the achievement of the performance condition is probable.

Valuations incorporate several variables, including expected term, expected volatility, expected dividend yield and a risk-free interest rate. We estimate the expected term of the options granted based on anticipated exercises in future periods. The expected stock price volatility for our stock options is calculated based on the historical volatility since the initial public offering of our common stock in March 2010. The expected dividend yield reflects our current and expected future policy for dividends on our common stock. To determine the risk-free interest rate, we utilize the U.S. Treasury yield curve in effect at the time of grant with a term consistent with the expected term of our awards.

Stock compensation expense is recognized by applying the expected forfeiture rate during the vesting period to the fair value of the award. The estimation of the number of stock awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from our current estimates, compensation expense may need to be revised. We consider many factors when estimating expected forfeitures for stock awards granted to employees, officers and directors, including types of awards, employee class, and an analysis of our historical forfeitures.

Revenue Recognition

We recognize revenue in accordance with SEC SAB No. 101, "Revenue Recognition in Financial Statements" ("SAB 101"), as amended by SAB No. 104, "Revenue Recognition" ("SAB 104") and FASB ASC 605, "Revenue Recognition" ("ASC 605"). Our product Neutrolin received its CE Mark in Europe in July 2013 and shipment of product to the dialysis centers began in December 2013. In accordance with SAB 101 and SAB 104, we recognize revenue from product sales when the following four revenue recognition criteria are met: persuasive evidence of an arrangement exists, delivery has occurred, the selling price is fixed or determinable, and collectability is reasonably assured. We recognize revenue upon shipment of product to the dialysis centers because the four revenue recognition criteria are met at that time. For an upfront payment related to an exclusive distribution agreement, we record it as deferred revenue and recognize revenue on a straight-line basis over the contractual term of the agreement

In October 2015, we shipped product with less than 75% of its remaining shelf life to a customer and issued a guarantee that any product shipped with less than 75% of its shelf life remaining would be replaced by us if the customer was not able to sell the product before it expired. As a result of this warranty, we may have an additional performance obligation (i.e. accept returned product and deliver new product to the customer) if the customer is unable to sell the short-dated product. Due to limited sales experience with the customer, we are unable to estimate the amount of the warranty obligation that may be incurred as a result of this shipment. Therefore, we have deferred the revenue and related cost of sales associated with the shipment of this product. Since we will be unable to resell the expired product if returned by the customer, the deferred revenue and related cost of sales is presented net as "Deferred revenue" on the consolidated balance sheet. At March 31, 2016, deferred revenue on the condensed consolidated

balance sheet amounted to $126,000.

Inventory Valuation

We engage third parties to manufacture and package inventory held for sale and warehouse such goods until packaged for final distribution and sale. Inventories are stated at the lower of cost or market price with cost determined on a first-in, first-out basis. Inventories are reviewed periodically to identify slow-moving or obsolete inventory based on sales activity, both projected and historical, as well as product shelf-life. In evaluating the recoverability of our inventories, we consider the probability that revenue will be obtained from the future sale of the related inventory and, if required, will write down inventory quantities in excess of expected requirements. Expired inventory is disposed of and the related costs are recognized as cost of product sales in our consolidated statements of operations.

We analyze our inventory levels to identify inventory that may expire prior to sale, inventory that has a cost basis in excess of its estimated realizable value, or inventory in excess of expected sales requirements. Although the manufacturing of our products is subject to strict quality controls, certain batches or units of product may no longer meet quality specifications or may expire, which would require adjustments to our inventory values.

In the future, reduced demand, quality issues or excess supply beyond those anticipated by management may result in an adjustment to inventory levels, which would be recorded as an increase to cost of product sales. The determination of whether or not inventory costs will be realizable requires estimates by our management. A critical input in this determination is future expected inventory requirements based on our internal sales forecasts which we then compare to the expiry dates of inventory on hand. To the extent that inventory is expected to expire prior to being sold, we will write down the value of inventory. If actual results differ from those estimates, additional inventory write-offs may be required.

Short-Term Investments

We determine the appropriate classification of marketable securities at the time of purchase and reevaluate such designation as of each balance sheet date. Investments in marketable debt and equity securities classified as available-for-sale are reported at fair value. Fair values of our investments are determined using quoted market prices in active markets for identical assets or liabilities or quoted prices for similar assets or liabilities or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Our marketable securities are highly liquid and consist of U.S. government agency securities, high-grade corporate obligations and commercial paper with maturities of more than 90 days but less than 12 months. Changes in fair value that are considered temporary are reported net of tax in other comprehensive income (loss). Realized gains and losses, amortization of premiums and discounts and interest and dividends earned are included in income (expense) on the condensed consolidated statements of operations and comprehensive income (loss). The cost of investments for purposes of computing realized and unrealized gains and losses is based on the specific identification method. Investments with maturities beyond one year, if any, are classified as short-term based on management’s intent to fund current operations with these securities or to make them available for current operations. For declines, if any, in the fair value of equity securities that are considered other-than-temporary, impairment losses are charged to other (income) expense, net. We consider available evidence in evaluating potential impairments of our investments, including the duration and extent to which fair value is less than cost and, for equity securities, our ability and intent to hold the investments.

Fair Value Measurements

We categorize our financial instruments into a three-level fair value hierarchy that prioritize the inputs to valuation techniques used to measure fair value. The fair value hierarchy gives the highest priority to quoted prices in active markets for identical assets (Level 1) and the lowest priority to unobservable inputs (Level 3). If the inputs used to measure fair value fall within different levels of the hierarchy, the category level is based on the lowest priority level input that is significant to the fair value measurement of the instrument. Financial assets recorded at fair value on our condensed consolidated balance sheets are categorized as follows:

- Level 1 inputs—Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.

- Level 2 inputs— Significant other observable inputs (e.g., quoted prices for similar items in active markets, quoted prices for identical or similar items in markets that are not active, inputs other than quoted prices that are observable such as interest rate and yield curves, and market-corroborated inputs).

- Level 3 inputs —Unobservable inputs for the asset or liability, which are supported by little or no market activity and are valued based on management's estimates of assumptions that market participants would use in pricing the asset or liability.

Recent Authoritative Pronouncements:

In May 2014, the FASB issued new guidance related to how an entity should recognize revenue. The guidance specifies that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods and services. In addition, the guidance expands the required disclosures related to revenue and cash flows from contracts with customers. The guidance is effective for us beginning in the first quarter of 2017. Early adoption is not permitted and retrospective application is required. We are currently evaluating the impact of adopting this guidance on our consolidated financial statements.

In June 2014, the FASB issued an accounting standard that clarifies the accounting for share-based payments when the terms of an award provide that a performance target could be achieved after the requisite service period. The standard requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. The amendments are effective for interim and annual reporting periods beginning after December 15, 2015. This adoption did not have a material impact on our consolidated financial statements.

In April 2015, the FASB issued new guidance which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. This guidance requires retrospective adoption and will be effective for us beginning in the first quarter of 2016. Early adoption is permitted. This adoption did not have a material impact on our consolidated financial statements.

In July 2015, the FASB issued an accounting standard that requires inventory be measured at the lower of cost and net realizable value and options that currently exist for market value be eliminated. The standard defines net realizable value as estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation and is effective for reporting periods beginning after December 15, 2016 and interim periods within those fiscal years with early adoption permitted. The guidance should be applied prospectively. We are evaluating the impact the adoption of this guidance will have on the determination or reporting of our consolidated

financial statements.

In November 2015, the FASB issued guidance that requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The current requirement that deferred tax liabilities and assets of a tax-paying component of an entity be offset and presented as a single amount is not affected by this amendment. The new guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016. Early adoption is permitted and the standard may be applied either retrospectively or on a prospective basis to all deferred tax assets and liabilities. We are evaluating the impact the adoption of this guidance will have on the determination or reporting of our consolidated financial statements.

On August 27, 2014 ASU No. 2014-15 – Presentation of Financial Statements, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern was issued. The ASU requires management to evaluate whether there are conditions and events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the financial statements are issued and if management's plans will alleviate that doubt. Management will be required to make this evaluation for both annual and interim reporting periods. The guidance is effective for annual periods ending after December 15, 2016 and interim periods thereafter. Early adoption is permitted.

In January 2016, the FASB issued a new standard that modifies certain aspects of the recognition, measurement, presentation, and disclosure of financial instruments. The accounting standard update is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017, and early adoption is permitted. We are currently assessing the impact that adopting this new accounting guidance will have on our consolidated financial statements.

In February 2016, the FASB issued new guidance related to how an entity should lease assets and lease liabilities. The guidance specifies that an entity who is a lessee under lease agreements should recognize lease assets and lease liabilities for those leases classified as operating leases under previous FASB guidance. Accounting for leases by lessors is largely unchanged under the new guidance. The guidance is effective for us beginning in the first quarter of 2019. Early adoption is permitted. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. We are evaluating the impact of adopting this guidance on our consolidated financial statements.

In March 2016, the FASB issued new guidance which clarifies the implementation guidance on principal versus agent considerations when reporting revenue gross versus net. The amendments in this update do not change the core principle of the new revenue guidance. The guidance is effective for us beginning in the first quarter of 2017. Early adoption is not permitted and retrospective application is required. We are currently evaluating the impact of adopting this guidance on our consolidated financial statements.

In March 2016, the FASB issued new guidance which simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The guidance is effective for us beginning in the first quarter of fiscal year 2017. Early adoption is permitted. We are evaluating the impact of adopting this guidance on our consolidated financial statements.

In April 2016, the FASB issued an update which clarifies two aspects of the new revenue guidance by providing guidance on how to identify performance obligations and providing implementation guidance surrounding licensing. The amendments in this update do not change the core principle of the new revenue guidance. The guidance is effective for us beginning in the first quarter of 2017. Early adoption is not permitted and retrospective application is required. We are currently evaluating the impact of adopting this guidance on our consolidated financial statements.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Item 3. Quantitative and Qualitative Disclosure about Market Risk.

None.

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Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer (who is our principal executive officer and principal financial officer), we carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of March 31, 2016. Based on the foregoing evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosures.

Disclosure controls and procedures are designed only to provide reasonable assurance that information to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. As of the end of the period covered by this report, our management, including our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures. Based on their evaluation of our disclosure controls and procedures, our management, including our chief executive officer (who is our principal executive officer and principal financial officer), have concluded that our disclosure controls and procedures were effective as of March 31, 2016 to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is (a) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (b) accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate to allow for timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended March 31, 2016, or in other factors that could significantly affect these controls, that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II
OTHER INFORMATION

Item 1. Legal Proceedings.

In February 2007, Geistlich Söhne AG für Chemische Industrie, Switzerland ("Geistlich") brought an action against the European Sodemann Patent covering our Neutrolin product candidate, which is owned by ND Partners, LLC ("NDP") and licensed to us pursuant to the License and Assignment Agreement between us and NDP. This action was brought at the Board of the European Patent Office ("EPO") opposition division (the "Opposition Board") based upon alleged lack of inventiveness in the use of citric acid and a pH value in the range of 4.5 to 6.5 with having the aim to provide an alternative lock solution through having improved anticoagulant characteristics compared to the lock solutions of the prior art. The Opposition Board rejected the opposition by Geistlich. On August 27, 2008, Geistlich appealed the court's ruling, alleging the same arguments as presented during the opposition proceedings.We filed a response to the appeal of Geistlich on March 25, 2009 requesting a dismissal of the appeal and maintenance of the patent as granted. On November 28, 2012, the Board of Appeals of the EPO (the "Appeals Board") held oral proceedings and verbally upheld the counterpart of the Sodemann Patent covering Neutrolin, but remanded the proceeding to the lower court to consider restricting certain claims of the counterpart of the Sodemann Patent. We received the Appeals Board's final

written decision on March 28, 2013, which was consistent with the oral proceedings. In a letter dated September 30, 2013, we were notified that the opposition division of the EPO reopened the proceedings before the first instance and gave their preliminary non-binding opinion that the patent as amended during the appeal proceedings fulfills the requirements of clarity, novelty, and inventive step, and invited the parties to provide their comments and/or requests by February 10, 2014. We filed its response on February 3, 2014 to request that the patent be maintained as amended during the appeal proceedings. Geistlich did not provide any filing by February 10, 2014; however, the Opposition Board granted Geistlich an extension to respond by the end of July 2014 because its representative did not receive the September 30, 2013 letter due to a change of address. Geistlich did not file a further statement within the required timeline. On November 5, 2014, the Opposition Division at the EPO issued the interlocutory decision to maintain the patent on the basis of the claims as amended during the appeal proceedings. This decision became final as no further appeal was lodged by Geistlich.

On September 9, 2014, we filed in the District Court of Mannheim, Germany a patent infringement action against TauroPharm GmbH and Tauro-Implant GmbH as well as their respective CEOs (the "Defendants") claiming infringement of our European Patent EP 1 814 562 B1, which was granted by the EPO on January 8, 2014 (the "Prosl European Patent"). The Prosl European Patent covers a low dose heparin catheter lock solution for maintaining patency and preventing infection in a hemodialysis catheter. In this action, we claim that the Defendants infringe on the Prosl European Patent by manufacturing and distributing catheter locking solutions to the extent they are covered by the claims of the Prosl European Patent. We believe that our patent is sound, and are seeking injunctive relief and raising claims for information, rendering of accounts, calling back, destruction and damages. Separately, TauroPharm has filed an opposition with the EPO against the Prosl European Patent alleging that it lacks novelty and inventive step. We cannot predict what other defenses the Defendants may raise, or the ultimate outcome of either of these related matters.

In the same complaint against the same Defendants, we also alleged an infringement (requesting the same remedies) of NDP's utility model DE 20 2005 022 124 U1 (the "Utility Model"), which we believe is fundamentally identical to the Prosl European Patent in its main aspects and claims. The Court separated the two proceedings and the Prosl European Patent and the Utility Model claims are now being tried separately. TauroPharm has filed a cancellation action against the Utility Model before the German Patent and Trademark Office based on the similar arguments as those in the opposition against the Prosl European Patent.

On March 27, 2015, the District Court held a hearing to evaluate whether the Utility Model has been infringed by TauroPharm in connection with the manufacture, sale and distribution of its TauroLock-HEP100TM and TauroLock-HEP500TM products. A hearing before the same court was held on January 30, 2015 on the separate, but related, question of infringement of the Prosl European Patent by TauroPharm.

The Court issued its decisions on May 8, 2015 staying both proceedings. In its decisions, the Court found that the commercialization by TauroPharm in Germany of its TauroLock catheter lock solutions Hep100 and Hep500 infringes both the Prosl European Patent and the Utility Model and further that there is no prior use right that would allow TauroPharm to continue to make, use or sell its product in Germany. However, the Court declined to issue an injunction in favor of us that would preclude the continued commercialization by TauroPharm based upon its finding that there is a sufficient likelihood that the EPO, in the case of the Prosl European Patent, or the German Patent and Trademark Office (the "German PTO"), in the case of the Utility Model, may find that such patent or utility model is invalid. Specifically, the Court noted the possible publication of certain instructions for product use that may be deemed to constitute prior art. As such, the District Court determined that it will defer any consideration of the request by us for injunctive and other relief until such time as the EPO or the German PTO has ruled on the underlying validity of the Prosl European Patent and the Utility Model.

Both the opposition proceedings against the Prosl European Patent before the EPO and the cancellation action against the Utility Model before the German PTO are ongoing. In its preliminary consideration of the matter, the EPO (and the German Patent and Trademark Office) regarded the patent as not inventive or novel due to publication of prior art. Oral proceedings before the Opposition Division at the EPO were held on November 25, 2015, at which the three judge patent examiner panel considered arguments related to the validity of the Prosl European Patent. The hearing was adjourned due to the fact that the panel was of the view that Claus Herdeis, one of the managing directors of TauroPharm, has to be heard as a witness in another hearing. A date for such further hearing has not been scheduled yet. As with the unfair competition matter, we expect that this matter will be under review and consideration by the Office for some time, with a determination not likely to be made before mid-2016. While we continue to believe that the referenced publication and instructions for use do not, in fact, constitute prior art and that the Prosl European Patent and the Utility Model validly claim inventions that will be found to be such by the EPO and the German PTO, there can be no assurance that we will prevail in this matter. The German PTO has scheduled a hearing in the cancellation proceeding for May 11, 2016 which has, however, been rescheduled to June 29, 2016 due to conflicting

court appointments of some members of the legal team. We therefore do not expect a decision from the German PTO in the Utility Model matter before mid- 2016, with any such decision also being subject to appeal.

On January 16, 2015, we filed a complaint against TauroPharm GmbH and its managing directors in the District Court of Cologne, Germany. In the complaint, we allege violation of the German Unfair Competition Act by TauroPharm for the unauthorized use of its proprietary information obtained in confidence by TauroPharm. We allege that TauroPharm is improperly and unfairly using its proprietary information relating to the composition and manufacture of Neutrolin, in the manufacture and sale of TauroPharm's products TauroLockTM, TauroLock-HEP100 and TauroLock-HEP500. We seek a cease and desist order against TauroPharm from continuing to manufacture and sell any product containing taurolidine (the active pharmaceutical ingredient ("API") of Neutrolin) and citric acid in addition to possible other components, damages for any sales in the past and the removal of all such products from the market. An initial hearing in the District Court of Cologne, Germany was held on November 19, 2015 to consider our claims. The judge made no decision on the merits of our complaint. On January 14, 2016, the court issued an interim decision in the form of a court order outlining several issues of concern that relate primarily to court's interest in clarifying the facts and reviewing any and all available documentation, in particular with regard to the question which specific know-how was provided to TauroPharm by whom and when. We have prepared the requested reply and produced the respective documentation. TauroPharm has also filed another writ to which we will have to reply by the end of April. A date for a further oral hearing has not been scheduled yet.

On July 7, 2015, a putative class action lawsuit was commenced against the Company and certain of its current and former officers in the United States District Court for the District of New Jersey, captioned Li v. Cormedix Inc., et al., Case 3:15-cv-05264. On September 4, 2015, two individuals, Shahm Martini and Paul Chretien (the "Martini Group"), filed a Motion to Appoint Lead Plaintiff. On that same date, another individual, Elaine Wood, filed a competing Motion to Appoint Lead Plaintiff. On September 18, 2015, the Martini Group withdrew its motion. Thereafter, on September 22, 2015, the Court appointed Elaine Wood as Lead Plaintiff and, on October 2, 2015, appointed the Rosen Law Firm as Lead Counsel.

On December 1, 2015, Lead Plaintiff filed an Amended Complaint asserting claims that the Company and Steven Lefkowitz, Randy Milby and Harry O'Grady (the "Cormedix Defendants") violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder and Section 20(a) of the Exchange Act. The Amended Complaint also names as defendants several unrelated entities that allegedly were paid stock promoters. Lead Plaintiff alleges generally that the Cormedix Defendants made materially false or misleading statements and omissions concerning, among other things, the competitive landscape for the Company's Neutrolin product and the alleged use of stock promoters. The Amended Complaint seeks unspecified damages, interest, attorneys' fees, and other costs.

On February 1, 2016, the Cormedix Defendants filed a motion to dismiss all claims asserted against them in the Amended Complaint on the grounds, among others, that the Amended Complaint fails to adequately allege: (1) material misstatements or omissions; (2) scienter by any of the Cormedix Defendants; or (3) loss causation. The parties are in the process of briefing that motion and oral argument currently is scheduled for July 18, 2016.

The Company believes that it has substantial legal and factual defenses to the claims in the class action and intends to continue vigorously defending the case.

Item 6. Exhibits.

The following is a list of exhibits filed as part of this Form 10-Q:

| Exhibit Number | Description |
|---|---|
| 3.1 | Bylaws, amended as of April 19, 2016.* |
| 10.1 | Second Extension of Executive Employment Agreement, as of April 29, 2016, by and between CorMedix Inc. and Randy Milby.* |
| 31.1 | Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.* |
| 32.1 | Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.* |
| 101 | The following materials from CorMedix Inc. Form 10-Q for the quarter ended March 31, 2016, formatted in Extensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets at March 31, 2016 and December 31, 2015, (ii) Condensed Consolidated Statements of Operations for the three months ended March 31, 2016 and 2015, (iii) Condensed Consolidated Statements of Changes in Stockholders' Equity for the three months ended March 31, 2016, (iv) Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2016 and 2015, and (v) Notes to the Unaudited Condensed Consolidated Financial Statements.** |

* Filed herewith.

** Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files in Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended and otherwise are not subject to liability under those sections.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

CORMEDIX INC.

| | | | | |
|---|---|---|---|---|
| Date: | May 10, 2016 | By: | /s/ Randy Milby | |
| | | | Name: | Randy Milby |
| | | | Title: | Chief Executive Officer<br>(Principal Executive Officer and Principal Financial and Accounting Officer) |

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